

RECEIVED
CENTRAL FAX CENTER

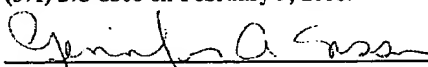
FEB 09 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ghisolfi, G.For: Recyclable Multilayer Material in Polyester
Resin

Serial No. 09/334,891

Filed: 6/17/1999

) Docket No. MG029A_US
) Art Unit: 1772
)) Examiner:
) Marc A. Patterson
)) I hereby certify that this correspondence is
) being facsimile transmitted to the United States
) Patent and Trademark Office to Fax Number
) (571) 273-8300 on February 9, 2006.
)) 
) Jennifer A. Sisson
)Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. EDWARD N. NOWAK

I, Edward N. Nowak, PhD, hereby declare that:

1. I am a resident of Hudson, Ohio and am employed as a Senior Staff Regulatory Scientist at M&G Polymers, USA. I have held that position for 4 years.
2. I am not an inventor of the subject matter disclosed or claimed in the subject patent application.
3. My educational background includes an Associate Science Degree in Chemistry from Holyoke Community College (1963); a Bachelor of Science from the University of Massachusetts (1965); and a PhD in Physical Organic Chemistry from the Pennsylvania State University (1970).
4. I have been employed for approximately 30 years by M&G Polymers USA, LLC, Shell Oil Company and The Goodyear Tire & Rubber Company in the capacity of administering compliance with food safety and environmental regulations. Previous to my current position as Senior Staff Regulatory Scientist, I was Staff Regulatory Chemist for Shell Oil Company from 1996 to 2002, Manager, Regulatory Compliance and Competitive Intelligence for Shell Chemicals from 1992 to 1996, Section Head Toxicology & Regulatory

Compliance for The Goodyear Tire & Rubber Company from 1988 to 1992, and Senior Chemist/Group Leader, Toxicology & Regulatory Compliance for The Goodyear Tire & Rubber Company from 1978 to 1988.

5. Prior to working in the regulatory positions delineated in paragraph 4 above, I was a Senior Chemist for The Goodyear Tire & Rubber Company for approximately 10 years.

6. I have served on many industry councils and coalitions including past Chairman of the Program Committee, The Society of the Plastics Industry Food, Drug and Cosmetic Packaging Committee and as a member of the Steering Committee of The Society of the Plastics Industry Food, Drug and Cosmetic Packaging Committee. I have also been a member of the Society of Toxicology and the American Chemical Society.

7. For the past 20 years I participated in shaping the global regulations for food packaging regarding what is and what is not safe and have advised management and scientists as to which materials may or may not be suitable for food packaging based on lack of regulatory recognition and safety. The advice and evaluations have been done on a global basis and includes but is by no means limited to the regulations of the United States, Japan, Canada, Mexico, Brazil, European countries on an individual basis and as the European Union.

8. A copy of my current resume is attached hereto as Exhibit A.

9. I have read the September 9, 2005 office action concerning the above mentioned patent application (Serial No. 09/334,891) and the prior art documents cited by the examiner as well as the additional prior art document now being called to the examiner's attention. These references include Roulin et al (U.S. Patent 5,508,075), Kimura et al (U.S. Patent 5,972,445), Wilson et al (U.S. Patent 3,170,832), and Wilson et al (U.S. Patent 2,961,418). In that office action of September 9, 2005, the examiner maintains that one of ordinary skill in the art would combine foamed "polyester" product of Wilson et al into the food package of Roulin et al based upon the use of Roulin et al's word polyester.

10. First, as one of ordinary skill in the art of polyester chemistry, I do not consider the "polyester" of Wilson '832 to be a polyester as defined by Roulin et al. The polyester of Wilson '832 is actually the reaction product of polyester resins and is not a polyester at all. The reaction product of the polyesters in Wilson '832 with the isocyanates is known as a

polyesterurethane or polyurethane to those of ordinary skill in the art. (See also the title of Wilson '418 claiming the composition to be a polyesterurethane). Wilson '832 describes the way to make the foamed "polyester resins" at column 1, lines 26-34. In that passage, the polyester resin is mixed with toluene di-isocyanate and water with a catalyst to permit a reaction to produce a foamed product. Comparing Wilson '832 with Wilson '418, it is apparent that the polyesters are reacted into different products¹ and in fact the polyesters themselves are aliphatic low molecular weight polyesters that are liquid (see '418 column 1, lines 24, Example 1 '418 column 2, line 18). This is because the foamed product of Wilson '832 is made using the teachings of Wilson '418 (column 1, lines 20-25).

11. The cured reaction product of the aliphatic polyesters of Wilson et al is also not recyclable. The curing process of the reacted polyesters of Wilson et al '832 is found at column 2, line 52- It is well known in the environmental field that articles which are cured such as polyurethanes and thermosets are not recyclable.

12. Neither Wilson reference teaches an aromatic polyester or a polyester containing ethylene glycol which includes those polyesters that are selected from the group consisting of polyethylene terephthalate and polyethylene terephthalate copolymers in which up to 20% of the moles derived from terephthalic acid are substituted by units deriving from isophthalic and/or naphthalene-dicarboxylic acid. Both Wilson references state that only certain polyesters ('832 column 1, line 20; '418 column 1, line 25) are capable of being foamed and that these certain polyesters are the reaction product of a polycarboxylic acid polyhydric alcohol ('832 column 1, line 16). The polyhydric alcohol is selected from the class described as di-, tri, or polyethylene glycol ('832 column 2, lines 46-47; '418, column 1, line 64 -65). Ethylene glycol, which is the glycol used in copolyethylene terephthalate, is known as mono-ethylene glycol (MEG) is not one of the glycols considered suitable by either Wilson reference.

13. It is well known the properties of the polyesterurethanes rely on the use of the polyhydric alcohol is selected from the class described as di-, tri, or polyethylene glycol. The use of these glycols excludes the use of ethylene glycol polyesters and therefore polyester selected from the group consisting of polyethylene terephthalate and polyethylene terephthalate copolymers in which up to 20% of the moles derived from terephthalic acid are

¹ The reaction product described in Wilson et al, is a polyurethane.

substituted by units deriving from isophthalic and/or naphthalene-dicarboxylic acid would not be considered one of those "certain polyesters" used in either Wilson reference. Additionally, the dibasic acids listed are succinic, adipic, azelaic ('418 column 1, line 61 and '832 column 2, line 44-45). These product of these diacids are aliphatic polyesters, not aromatic polyesters.

14. As one of extraordinary skill in the art of food packaging safety in general and specifically of the safety and regulation of polyesters for food packaging, I can state that, at the time of the current invention, one of ordinary skill in the art would not have chosen the polyesterurethanes taught in either cited Wilson references for use in food packaging intended for applications taught in the current invention.

The basis of the Wilson invention is the reaction of aromatic diisocyanates, e.g., toluene diisocyanate with low molecular weight aliphatic polyesters and polyols, e.g., diethyleneglycol to form polyesterurethanes. Such diisocyanates exhibit well-known toxicological properties which strongly argue against their being used as components of food packaging. Of particular note is that toluene diisocyanate has, with only two exceptions, the lowest Threshold Limit Value (0.005 ppm) among the approximately 750 chemicals, including some well-established human carcinogens, for which TLVs have been established by the American Conference of Governmental Industrial Hygienists. TDI is a potent sensitizer and few exposures to significant levels or repeated exposures to low levels may sensitize an individual such that subsequent exposure to an extremely low level would induce a potentially life-threatening allergic reaction.

TDI is regulated by the FDA for very limited uses that do not provide significant opportunities for migration of residual TDI to food. Specifically TDI is regulated for use as a component of urethane adhesives in 21 CFR 175.105. This regulation presupposes that the only contact the regulated substance has with food is that which may occur along the edge of a seam where two surfaces are bonded. TDI is also regulated under 21 CFR 177.1680 for use in bulk containers for dry foods. The large volume-to-surface area and the very limited tendency of dry foods to extract packaging components mitigate against significant exposure to TDI.

Such would not be the case for the envisioned applications of the current invention in which a variety of aqueous, fatty and acidic foods which have greater propensity to extract

packaging components. The higher surface area of a foam sheet would certainly exacerbate the migration of packaging components.

Accordingly, one of ordinary skill in the art would not seek to utilize TDI (or related diisocyanates) in polyester foam intended for the applications taught in the current invention.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

Respectfully submitted,



Edward N. Nowak, PhD

February 8, 2006

FEB 09 2006

EXHIBIT A - Resume

Edward N Nowak
6951 Ridge Road
Sharon Center, OH 44274
Phone: +330 239 7450
Fax: +330 239 7403
Email: ed.n.nowak@gruppomgus.com

Summary of qualifications

2002-Present M&G Polymers USA, LLC Sharon Center, OH
Senior Staff Regulatory Scientist

- Responsible for developing, managing and directing Product Stewardship program for the PET business
- Responsible for regulatory compliance of PET resins with US FDA, USEPA (TSCA), US DOT, US OSHA (Hazard Communication) European (EEC) and global food packaging regulations.
- Provide recommendations to senior management regarding regulatory compliance of new and existing products.
- Support Sales/Marketing by providing customer assurance of regulatory compliance of PET products.
- Provide advice and guidance to R&D management and staff in the design of new polyester products and in the selection of modifiers and additives to assure compliance with global regulations.
- Provide training and guidance to Point Pleasant Plant to assure that equipment and process modifications do not create violations of EPA TSCA regulations.
- Design and conduct laboratory testing programs to assess compliance of new products with global food contact regulations.
- Maintain a Type III Drug Master File for PET products to support customers' New Drug Applications.
- Develop and implement programs to generate chemistry, toxicology and environmental data on new polymers for inclusion in petitions for governmental approval.
- Prepare and submit petitions to US FDA and European EFSA to amend regulations to clear use of new polymers in packaging applications. Interact with FDA and EFSA throughout regulatory process.
- Generate Material Safety Data Sheets for Polyester resins, by-products and waste streams.
- Represent the PET business in trade and professional organizations:
 - Plastics Europe Food Contact Committee
 - Plastics Europe PET Health, Safety and Environmental Committee
 - PETRA Product Stewardship Committee
 - Association of Plastics Recyclers Technical Committee
 - National Association for PET Container Resources Technical Committee.

Work Experience

1996 - 2002

Shell Chemicals

Akron OH

Staff Regulatory Scientist

- Responsible for developing, managing and directing Product Stewardship program for the PET business
- Responsible for regulatory compliance of PET resins with US FDA, USEPA (TSCA), US DOT, US OSHA (Hazard Communication) and global food packaging regulations.
- Provide recommendations to senior management regarding regulatory compliance of new and existing products.
- Support Sales/Marketing by providing customer assurance of regulatory compliance of PET products.
- Provide advice and guidance to R&D management and staff in the design of new polyester products and in the selection of modifiers and additives to assure compliance with global regulations.
- Provide training and guidance to Point Pleasant Plant to assure that equipment and process modifications do not create violations of EPA TSCA regulations.
- Design and conduct laboratory testing programs to assess compliance of new products with global food contact regulations.
- Maintain a Type III Drug Master File for PET products to support customers' New Drug Applications.
- Develop and implement programs to generate chemistry, toxicology and environmental data on new polymers for inclusion in petitions for governmental approval.
- Prepare and submit petitions to US FDA to amend regulations to clear use of new polymers in packaging applications. Interact with FDA throughout regulatory process.
- Provide advice and consultation to other Shell Chemical businesses (Kraton, Carilon, polybutylene) on regulatory compliance issues for food contact materials.
- Generate Material Safety Data Sheets for Polyester resins, by-products and waste streams.
- Represent the PET business in trade and professional organizations:
 - The Society of the Plastics Industry Food, Drug and Cosmetic Packaging Materials Committee
 - The American Plastics Council Product Stewardship Work Group
 - The Coalition for PET Safety
 - The National Center for Food Safety and Technology Plastics Working Group.

1992 - 1996

Shell Chemicals

Akron OH

Manager, Regulatory Compliance and Competitive Intelligence

- Member of Polyester R&D Management Team
- Responsible for managing a team of 6 professional and support staff, with

annual budget of \$600,000.

- In addition to responsibilities listed above,
 - directed corporate Competitive Intelligence activities (collection and evaluation of competitor information),
 - directed R&D facility safety and regulatory compliance (hazardous waste disposal, OSHA compliance EPA reporting obligations, industrial hygiene, medical) program, and
 - directed purchasing/shipping/ receiving section.

1988 - 1992 The Goodyear Tire & Rubber Company Akron OH

Section Head Toxicology & Regulatory Compliance

- Responsible for Management of Toxicology and Regulatory Compliance Section comprised of 4 professionals and one technician with annual budget of \$340,000.
- Responsible for development of in-house toxicity testing facility to evaluate toxicity of new and existing rubber chemicals, PET resins, and PVC additives. Testing capabilities included three *in vitro* and one *in vivo* mutagenicity test systems, a short-term aquatic toxicity test, and a reproductive (teratogenicity) screening test.
- Responsible for interfacing with outside contract toxicity testing labs, including test protocol selection, study monitoring, evaluation and interpretation of test results.
- Represented Goodyear on Chemical Manufacturers Association Rubber Additives Panel in the design and oversight of major toxicity testing of rubber chemicals in compliance with EPA Section 4 test rules.
- Member of Goodyear Corporate toxicology Committee (with Manager, Industrial Hygiene, Manager, Corporate health dept, Manager, corporate safety dept). reporting to Vice President, Government Environmental Safety and Health Assurance on health, safety and legal issues, including TSCA Section 8E substantial risk notifications and TSCA Section 8c allegations.
- Provided regulatory compliance support to Sales/Marketing and R&D as described above for PET business, PVC business, Rubber Chemicals business and Industrial Products business.

1978 - 1988 The Goodyear Tire & Rubber Company Akron OH

Senior Chemist/Group Leader, Toxicology & Regulatory Compliance

- Responsible for coordination of genotoxicity testing of rubber chemicals and industrial products.
- Provided regulatory compliance support to Sales/Marketing and R&D as described above.

1969 - 1978 The Goodyear Tire & Rubber Company Akron OH

Senior Chemist, Organic Chemicals Dept.

- Responsible for development of new monomers for synthetic rubber.

- Responsible for development of new processes for manufacture of rubber chemicals. Specific research activities included development of new chemical process and implementation in Bayport Hydroquinone plant.

Education

1970 Ph.D. The Pennsylvania State University
Physical Organic Chemistry.

1965 B.S. The University of Massachusetts
Chemistry

1963 Assoc., Science Holyoke Community College
Science (Chemistry)

Professional memberships

Chairman, Program Committee, The Society of the Plastics Industry Food, Drug and Cosmetic Packaging Committee (1997, approx)

Member, Seering Committee, The Society of the Plastics Industry Food, Drug and Cosmetic Packaging Committee (1995-1996, approx)

Member, Society of Competitive Intelligence Professionals (1992-1996)

Member, Society of Toxicology (1988-1992, approx.)

Member, American Chemical Society (1968-1980, approx.)